REMARKS

Claims 1-2 and 5-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 19-29 of copending Application No. 10/806,260.

Claims 1-2, 5-10, 12, 14 and 18-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/805,806.

Submitted herewith is Applicants' terminal disclaimer with regard to copending Application Nos. 10/806,260 and 10/805,806.

With regard to 35 U.S.C. 103(a), Applicants acknowledge the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made. Applicants advise that all the claims were commonly owned at the time any inventions covered herein were made.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryans et al. (US 7,141,606) in view of Berge et al. (J. of Pharmaceutical Sciences, 66, no. 1, Jan. 1977, p. 1-19).

Bryans et al. disclose a method of treating insomnia by administering a therapeutically effective amount of (3S,4S)-(1-Aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid or a pharmaceutically acceptable salt thereof. The compound recited above can be gabapentin. As the Examiner indicates, the present invention differs from Bryans et al. in that the formation of gabapentin tannate is not disclosed.

With regard to Berge et al., Table I lists approximately 70 FDA-approved commercially marketed salts including tannate. It is interesting to note that of all the salts in use through 1974, tannate salts represented only 0.88% usage. The Berge et al. reference does not disclose gabapentin as a potential compound to be modified. (See Table III)

Specifically, regarding the rejection of claims 1-2 and 5-6 based on §103(a), the Examiner indicated that Bryans et al. expressly disclose that it seems reasonable to form the organic salt forms of gabapentin for sleep disorders based on col. 10, lines 33-37, which reads:

> Since amino acids are amphoteric, pharmacologically compatible salts when R is hydrogen can be salts of appropriate inorganic or organic acids, for example, hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid, and ascorbic.

The Examiner then indicated that Berge et al. expressly describe various FDA-approved commercially marketed salts among which the tannate is displayed as one of the potential candidates for the pharmaceutical compounds. The Examiner then concludes that it would have been obvious to the skillful artisan in the art to be motivated to use the tannate for the salt of gabapentin for sleep disorders; this is because Berge et al. expressly teaches that one of the 70 FDA-approved commercially marketed salts can be the tannate.

Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness in light of the recent decision in *KSR International Co. v. Telefax Inc. and Technology Holding Co.,* No. 04-1350, 550 U.S. _____ (2007), in addition to the four criteria set forth in Graham v. John Deere Co., 383 U.S. 1148 USPQ 459 (1966), the Examiner must determine "whether there was an apparent reason to combine" the prior art references to derive the claimed invention. The reason to make the claimed combination must be found in the prior art, and not based on Applicants' disclosure. Failure to show any of the foregoing negates a *prima facie* showing of obviousness.

The invention as defined in claim 1 is gabapentin tannate. It is the Examiner's position that one skilled in the art would be able to just pick the tannate salt of the claimed invention from the laundry list provided in the Berge et al. reference. This is unlikely because even Berge et al. state that "choosing the appropriate salt ... can be a

very difficult task, since each salt imparts unique properties to the parent compound." (See page 1, col. 1, last sentence.) Berge et al. further state that "there is no reliable way of predicting the influence of a particular salt species on the behavior of the parent compound." (See page 1, col. 2, lines 7-9.) Furthermore, the Examiner fails to appreciate that the most commonly used salt in Berge et al. is hydrochloride at 42.98% usage compared to tannate at 0.88% usage. Consequently, Applicants assert that the Berge et al. reference teaches away from combining gabapentin with tannic acid to produce gabapentin tannate.

Merely identifying all of the elements of a claim or their equivalents in the prior art is not sufficient. Many inventions are combinations of old elements, and an Examiner may often find every element of a claimed invention in the prior art. If this finding were sufficient "to negate patentability, very few patents would ever issue." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Therefore, in order to establish a *prima facia* rejection for obviousness, an "examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998).

Taking into consideration the following:

1) Bryans et al. disclose gabapentin (not gabapentin tannate) for treating insomnia. There is no mention of a tannate salt of gabapentin in Bryans et al.

2) Berge et al. disclose a laundry list of FDA approved salts including tannate at a usage of 0.88% compared to a usage of 42.98% for hydrochloride salts with no mention of gabapentin; and

3) Applicants state in the present application that, while it is known that the formation of tannate salts with active pharmaceutical ingredients proceeds via a reaction of the amine groups or other basic functional groups of the active ingredient with the carboxylic or hydroxyl group present in tannic acid. In the gabapentin compound, the close proximity of a carboxylic acid group to the

positively charged amine functional group was expected to prevent the formation of the tannate salt. (See page 4, first full paragraph of the present specification.)

In summary, there is no reason alluded to in either of the cited references that would cause one of ordinary skill in the art to combine the references in the manner suggested by the Examiner. Accordingly, Applicant submits that claims 1-2 and 5-6 are patentable over the cited references. Applicants believe that, based on the arguments submitted herewith and the enclosed terminal disclaimer, pending claims 1-21 are patentable and in condition for allowance. Such action is respectfully requested.

Respectfully submitted,
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